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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/397,558	09/16/99	LAL	P PF-0527-1DIV

EXAMINER	
HARRIS, A	
ART UNIT	PAPER NUMBER
1642	13

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LEGAL DEPARTMENT
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/397,558	Lal et al.
Examiner	**Group Art Unit**
Alana M. Harris, Ph. D.	1642

☒ Responsive to communication(s) filed on *November 20, 2000.*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1, 2, 14-18, and 21-32* is/are pending in the applicat

Of the above, claim(s) *14-18, 23-26, and 30-32* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 2, 21, 22, and 27-29* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response to Amendment

1. Claims 1, 2, 14-18 and 21-32 are pending.

Claim 1 has been amended.

Claims 28-32 have been added.

Claims 14-18, 20, 23-26 and 30-32, drawn to non-elected inventions are withdrawn from examination.

Claims 1, 2, 21, 22 and 27-29 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 U.S.C. § 102

3. The rejection of claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by either Yu et al. (Genome Res. 7(4):353-8, 1997) or Andersson et al. (Anal. Biochem. 236(1):107-113, 1996), as evidenced by Accession #O75539 is withdrawn due to Applicants' amendment. The

Examiner thanks the Applicants for drawing her attention to referencing the wrong sequence in Paper #11, mailed August 16, 2000.

Claim Rejections - 35 U.S.C. § 103

4. The rejection of claim 27 under 35 U.S.C. 103(a) as being unpatentable over Accession #Q20236, Yu et al. and Andersson et al. in view of Harlow and Lane (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, 1988) is withdrawn due to the amendment of claim 1.

Maintained Rejections and New Grounds of Rejection

Claim Rejections - 35 U.S.C. § 112

5. The rejection of claims 1, 2, 21, 22 and 27 and newly added claims 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained and made.

Applicants argue "...that at least 72% of the tissue libraries in which PGAMP-1 was detected were cancerous or immortalized..., and at least 76% of the tissue libraries in which PGAMP-2 was detected were cancerous or immortalized... Applicants submit that because the expression of *the claimed polypeptides are specific, to a statistically significant degree*, to a cancerous tissue, a person of skill in the art would know how to use these polypeptides for the identification of cancerous tissue. *Although these polypeptides are not expressed solely in*

cancerous tissue, they could still be used for indicating, with a reasonable chance of success, whether any particular tissue tested was cancerous." This is found unpersuasive.

To determine if results should be deemed statistically significant one skilled in the art must know sample size, how many times the experiment has been repeated, variability within the sample pool and what was the amount of error. None of the that information has been provided within the specification, hence the Examiner can only treat Applicants assertion as an opinion. Further, Applicants own submission admits to the fact that these polypeptides are not expressed solely in cancerous tissue so the applicability of the proteins is still at question. One skilled in the art can not rely on Applicants expressed opinions and the percentages recited in the specification and in Applicants' arguments of Paper 12, pages 6 and 7 as definitive proof that SEQ ID Nos:1 and 2 as compounds that possibly can be used as diagnostic tools, therapeutics agents or as pharmaceutical agents. Thus, undue experimentation would be required to use the instantly claimed polypeptides.

6. The rejection of claim 2 under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement commensurate with the scope of the claimed invention is maintained.

Applicants argue that "[i]t would be routine for a person of ordinary skill in the art to make any of the claimed polypeptide variants having at least 90% sequence identity to SEQ ID NO:1 or SEQ ID NO:2...". This is found unpersuasive.

The Examiner agrees with the Applicants that any person of ordinary skill in the art could make the claimed variants, however the burden is great as to the number of variants that would need to be screened and identified that have activity and possess the function of the alleged proteins. Applicants are not entitled to all polypeptide variants that have at least 90% sequence identity. And even though "Applicants submit that polypeptide variants which, due to alternative splicing or post-translational modifications, would be significantly different, structurally and functionally, from the claimed polypeptides of SEQ ID NO:1 or SEQ ID NO:2..." this does not absolve Applicants from the lack of enablement for variants that have at least 90% sequence identity.

Claim Rejections - 35 U.S.C. § 101

7. The rejection of claims 1, 2, 21, 22 and 27 and newly added claims 28 and 29 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility is made and maintained.

Applicants argue that "... the statutory standard for the utility requirement does not require that a claimed invention have an asserted utility which is perfect in every regard, but that a person of ordinary skill in the art would **more likely than not** find that an asserted utility was credible." This argument has been carefully considered and this is not considered persuasive.

The Examiner has reviewed the Guidelines for Examination of Applications for compliance with the Utility Requirement of the Official Gazette, vol 1242, January 30, 2001.

Looking at page 1242 OG 167, II, section B, number 1 first and foremost the claims must be reviewed and the Applicant must have a supporting written description. Applicants do not have supporting written description for the reasons stated in the maintained 112 first paragraph rejection and of record. The credibility and the specificty of the asserted utility is undermined when the claimed polypeptides have yet to be definitively characterized. The specification does not support the use of these claimed PGAMPs as selective markers for just prostate cancer or as compounds to be used in the treatment of prostate disorders and/or cancer.

Claims 1, 2, 21, 22 and 27-29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reason set forth above, one skilled in the art clearly would not know how the use the claimed invention.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703)306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 3:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703)308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-0196.

Alana M. Harris, Ph.D.
Patent Examiner, Group 1642
February 7, 2001

Sheela Huff

SHEELA HUFF
PRIMARY EXAMINER